Billing Code: 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day-12-0814]

Proposed Data Collections Submitted for

Public Comment and Recommendations

In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the Centers for Disease Control and Prevention (CDC) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the data collection plans and instruments, call 404-639-7570 or send comments to Kimberly Lane, CDC Reports Clearance Officer, 1600 Clifton Road, MS D-74, Atlanta, GA 30333 or send an email to omb@cdc.gov.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on

respondents, including through the use of automated collection techniques or other forms of information technology. Written comments should be received within 60 days of this notice.

Proposed Project

CDC Cervical Cancer Study (CX3)(OMB No. 0920-0814, exp. 6/30/2012) – Revision - National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The National Breast and Cervical Cancer Early Detection Program (NBCCEDP) is the only organized national screening program in the United States. The program offers breast and cervical cancer screening to underserved women. Given resource limitations, the screening standards for cervical cancer in the program include an annual Pap test until a woman has had three consecutive normal Pap tests, at which time the Pap test frequency is reduced to every three years. HPV DNA testing has been approved in the U.S. as a secondary screening tool for ASCUS (Atypical Squamous Cells of Undetermined Significance), and as a primary screening tool for women 30 years of age and older, but it is not currently a reimbursable expense under program guidelines. Adopting HPV testing along with Pap testing

in women over 30 could help the program better utilize resources by extending the screening interval of women who are cytology negative and HPV test negative, which is estimated to be 80-90% of women. In 2005, the NBCCEDP convened an expert panel to determine policies on reimbursement of the HPV DNA test with the Pap test (co-test) for primary screening. The panel recommended that the program not reimburse for the HPV DNA test but instead requested that pilot studies be performed to measure the feasibility, acceptability and barriers to use of the test.

A pilot study, the CDC Cervical Cancer Study (CX3), is currently being conducted in 15 clinics in the state of Illinois. A total of 2,246 women between the ages of 30 and 60 who visited one of the participating clinics for routine cervical cancer screening were recruited for the study. Patients who agreed to participate in the study received an HPV DNA test in addition to the Pap test. The clinics were assigned to one of two study arms. Clinics in the intervention group administered the HPV DNA tests to eligible patients, along with a multi-component educational intervention involving both providers and patients. Clinics in the comparison group administered the HPV tests but patients and providers did not receive the educational intervention.

The purpose of the CX3 study is to examine whether or not there is an increase in the cervical cancer screening interval

to three years for women in the target age range with a normal Pap test and a negative HPV DNA test. Primary goals of the study are to: (1) assess whether provider and patient education will lead to extended screening intervals for women who have negative screening results; (2) identify facilitators and barriers to acceptance and appropriate use of the HPV test and longer screening intervals; (3) track costs associated with HPV testing and educational interventions; and (4) identify the HPV genotypes among this sample of low income women. Secondary goals of the study are to: (1) assess follow-up of women with positive test results and (2) determine provider knowledge and acceptability of the HPV vaccine.

During the first three years (Phase I) of the study, data were collected from a number of sources. Completed data collection activities include: before beginning patient recruitment a provider baseline survey was administered to providers at the participating clinics who routinely perform Pap testing; a patient baseline survey was administered to a sample of patients during their initial clinic visit prior to the patient's HPV test; a monthly clinic survey was administered to all participating clinics during the first year of patient recruitment to obtain information regarding resources associated with participating in the study; and a provider follow-up survey was administered to clinic providers 12 months following study

initiation. In addition, information collection for an 18-month follow-up survey was initiated among patients who completed a baseline survey.

Approval is currently being requested to continue data collection during Phase II of the study. These data collection activities include: continuing administration of the patient follow-up survey 18 months following the patient's initial clinic visit; administration of a provider follow-up survey 36 months following study initiation; and conducting qualitative interviews with providers to identify facilitators and barriers to acceptance and appropriate use of the HPV test and longer screening intervals. The follow-up surveys for patients and providers will assess changes in knowledge, attitudes, beliefs and behavior regarding cervical cancer screening. An additional source of data for the analysis includes patient medical and billing records, which will be reviewed to provide information necessary to determine whether or not HPV co-testing leads to extended screening intervals for women with negative results (and to determine what type of follow-up care was provided to women with positive HPV test results).

The results of this study will provide information regarding the extent to which providers are willing to extend the cervical cancer screening interval to three years for women in the target age range with a normal Pap test and a negative

HPV DNA test. It will also provide information regarding whether provider and patient education will lead to extended screening intervals for women who have negative screening results. In addition, the study results will provide information regarding the level of knowledge regarding cervical cancer screening among low-income, underserved women—who represent the demographic most needy of highly sensitive screening methodologies that can increase the likelihood of detecting cervical dysplasia at less frequent screening intervals. The findings from this study will help inform standards regarding the HPV DNA test on a national level for cervical cancer screening in the NBCCEDP. Participation in the CX3 study is voluntary and there are no costs to respondents other than their time. OMB approval is requested for one year.

Estimated Annualized Burden Hours

Type of Respondent	Form Name	No. Respondents	No. Responses per Respondent	Average Burden per Response (in hours)	Total Burden (in hours)
Patients	Follow-up Patient Survey	150	1	10/60	25
Providers	Follow-up Provider Survey	70	1	30/60	35
	Focus Group Moderator Guide	75	1	1	75
				Total	135

Date: February 10, 2012

_____

Ronald Otten
Deputy Chief
Centers for Disease Control and Prevention

[FR Doc. 2012-3620 Filed 02/16/2012 at 8:45 am; Publication Date: 02/17/2012]